



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,394	03/29/2002	Haifeng Chen	226272007801	5216
25226	7590	11/17/2005	EXAMINER	
MORRISON & FOERSTER LLP			MARVICH, MARIA	
755 PAGE MILL RD			ART UNIT	
PALO ALTO, CA 94304-1018			PAPER NUMBER	

1633

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,394

Applicant(s)

CHEN ET AL.

Examiner

Maria B. Marvich, PhD

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-31 is/are pending in the application.
- 4a) Of the above claim(s) 19-23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4-18 is/are allowed.
- 6) ☒ Claim(s) 24-29 and 31 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to an amendment filed 8/23/05. Claims 1-3 have been cancelled. Claims 4, 5, 12, 25-28, 30 and 31 have been amended. Claims 19-23 have been withdrawn. Claims 4-18 and 24-31 are under examination in this application.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were not necessitated by applicants' amendment and therefore, this action is not final.

Drawings

Figures 6 and 7 are objected to under 37 CFR 1.83(a) because they fail to show any details as described in the specification. Specifically, both figures are graphs. However, the black bars are presented on a black background. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. **This is a new objection.**

Claim Objections

Claim 30 is objected to because of the following informalities: In claim 30, line 1, “recombinant rAAV” is redundant as rAAV is defined as “recombinant AAV” in the specification. Appropriate correction is required. **This is a new objection.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 24-29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection.**

Claim 24 is vague and indefinite in that the metes and bounds of “(T)he vector according to claim 15” are unclear. While claim 24 is drawn to a vector, it depends from claim 15, which is drawn to a method that uses an adenoviral vector to produce rAAV. Therefore, it is unclear if claim 24 is actually intended on limiting the method by reciting that the vector provides helper functions as recited in the Markush group of adenoviral genes or if it is drawn to the vector. If applicants intend on reciting the vector, claim 24 does not further limit claim 15.

Claims 25-29 are vague and indefinite in that the metes and bounds of “transcription of the AAV *rep* gene is promoted less than 50% (25%, 15%, 10%) of wildtype P5 promoter” are unclear. It is unclear if applicants are comparing the level of transcription of the *rep* gene that is promoted by the minimal promoter, minimal Drosophila heat shock protein or the minimal adenoviral E1b promoters to the amount of physical promoter in the cell or to the level of

Art Unit: 1633

transcription that would be produced in the cell by the AAV p5 promoter if rep were under control of the AAV p5 promoter.

Claim 31 is vague and indefinite in that the metes and bounds of “much” are unclear. The term “much” is a relative one not defined by the claim, no single set of conditions is recognized by the art as being “much lower” and because the specification does not provide a standard for ascertaining the requisite degree, the metes and bounds of this claim cannot be established

Conclusion

Claims 4-18 are allowable.

Claims 24-29 and 31 are rejected. Claim 30 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, David Nguyen, PhD can be reached on (571)-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
Art Unit 1633

November 14, 2005



DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER